DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: **03-024**

2. STATE: Washington

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

RECEIVED
OCT 28 2003

4. PROPOSED EFFECTIVE DATE
October 1, 2003

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:

7. FEDERAL BUDGET IMPACT:
a. FFY 2003 $0
b. FFY 2004 $0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Adding a Supplemental Drug Rebate Agreement template to Supplement A to Attachment 4.19-B

Attachment 3.1A, page 5-2 (P+I)
Attachment 3.1B, page 4-3 (P+I)

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:

Attachment 3.1A, page 5-2 (P+I)
Attachment 3.1B, page 4-3 (P+I)

Washington (03-024)
approved: 01/22/04
effective: 10/01/03

10. SUBJECT OF AMENDMENT:

Add a Supplemental Drug Rebate Agreement template

11. GOVERNOR'S REVIEW *(Check One)*:
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED: Exempt

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME:
DENNIS BRADDOCK

14. TITLE:
Secretary

15. DATE SUBMITTED:
10-27-03

16. RETURN TO:
Department of Social and Health Services
Medical Assistance Administration
925 Plum St SE MS: 45533
Olympia, WA 98504-5533

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: OCT 28 2003

18. DATE APPROVED: JAN 22 2004

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: OCT - 1 2003

20. SIGNATURE OF REGIONAL OFFICIAL: /S/

21. TYPED NAME: Karen O'Connor

22. TITLE: Associate Regional Administrator
Division of Medicaid & Children's Health

23. REMARKS:

Pen + Ink changes authorized by the State on 12/1/03.

FORM HCFA-179 (07-92)

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State WASHINGTON

12. a. Prescribed Drugs (Cont.)

(8) Prior authorization programs for covered outpatient drugs provide for a response within 24 hours of a request for prior authorization and provides for the dispensing of at least a 72-hours supply of medications in emergency situations.

Therapeutic Consultation Service (TCS)

(9) In the Therapeutic Consultation Service (TCS), all Medicaid recipients will have their entire drug profile reviewed by clinical pharmacists after the fifth request for a brand-name drug is processed in a calendar month or anytime a request for a non-preferred drug is processed. A non-preferred drug is a drug in a drug class that has essentially the same clinical safety and efficacy as the drug of choice, but is not the preferred drug. TCS is not a limit, but rather a service to provide a clinical pharmacy review of the client's entire drug therapy. This review is conducted to assure that Medicaid clients are receiving appropriate drug therapy, without therapeutic duplication or without potentially serious drug-drug interactions or drug-disease conflicts. Prescribers direct clients' drug therapy and have the final say. Reports will be available that indicate the numbers of prescriptions that were dispensed as originally ordered by the prescriber.

Supplemental Rebate Agreement

(10) The state is in compliance with Section 1927 of the Act. The state will cover drugs of manufacturers participating in the Medicaid Drug Rebate Program. Based on the requirements for Section 1927 of the Act, the state has the following policies for drug rebate agreements:

- Manufacturers are allowed to audit utilization rates.
- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927 (b)(3)(D).
- A rebate agreement between the state and a drug manufacturer for drugs provided to the Washington Medicaid population, submitted to CMS on January 14, 2002, entitled "State of Washington Supplemental Rebate Contract," has been authorized by CMS.
- A rebate agreement between the state and a drug manufacturer for drugs provided to the Washington Medicaid population, submitted to CMS on January 16, 2004, entitled "State of Washington Supplemental Rebate Contract," has been authorized by CMS.
- The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any cash state supplemental rebates collected on the same percentage basis applied under the national rebate agreement.
- All drugs covered by the program, irrespective of a prior authorization agreement, will comply with provisions of the national drug rebate agreement.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State WASHINGTON

12.a. Prescribed Drugs (Cont.)

Preferred Drug List

- Pursuant to 42 U.S.C. section 1396r-8, the State is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list. Prior authorization programs for covered outpatient drugs provide for a response within 24 hours of a request for prior authorization, and provides for the dispensing of at least a 72-hour supply of medications in emergency situations, in accordance with provisions of section 1927(d)(5) of the Social Security Act. The prior authorization process is described in chapter 388-530 WAC.
- Prior authorization will be established for certain drug classes or particular drugs in accordance with Federal law. All drugs covered by the program, irrespective of a prior authorization requirement, will comply with the provisions of the national drug rebate agreement.
- A preferred drug list does not prevent Medicaid beneficiaries from obtaining access to medically necessary drugs of manufacturers that participate in the national drug rebate program.
- The State will utilize the Drug Utilization Review board to assure, that in addition to pricing consideration, preferred drugs are clinically appropriate.

Mail Order Delivery Service for Prescription Drugs

(11) The state contracts for a mail-order delivery service for prescription drugs through a competitive bid process. This service is available to all fee-for-service Medicaid clients statewide. Clients have the option of having prescriptions filled at either a local retail outlet of their choice or by the mail-order contractor.

All policies and procedures that apply to retail pharmacies also apply to the mail-order contractor, except for the following:

(A) The mail-order contractor is reimbursed at a mutually agreed upon level that is less than reimbursement provided to local retail pharmacies; and

(B) If authorized by the prescriber, the mail-order contractor may dispense the following drugs in up to a ninety-day supply:
  (i) Preferred drugs identified by the state;
  (ii) Generic drugs; and
  (iii) Drugs that do not require prior authorization or expedited prior authorization.

b. Dentures
Prior approval for cast base partial dentures

c. Prosthetic devices
  (1) Prior approval
  (2) Hearing aids provided on the basis of minimal decibel loss

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State WASHINGTON

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(9) In the Therapeutic Consultation Service (TCS), all Medicaid recipients will have their entire drug profile reviewed by clinical pharmacists after the fifth request for a brand-name drug is processed in a calendar month or anytime a request for a non-preferred drug is processed. A non-preferred drug is a drug in a drug class that has essentially the same clinical safety and efficacy as the drug of choice, but is not the preferred drug. TCS is not a limit, but rather a service to provide a clinical pharmacy review of the client's entire drug therapy. This review is conducted to assure that Medicaid clients are receiving appropriate drug therapy, without therapeutic duplication or without potentially serious drug-drug interactions or drug-disease conflicts. Prescribers direct clients' drug therapy and have final approval. Reports will be available that indicate the numbers of prescriptions that were dispensed as originally ordered by the prescriber.

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- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927 (b)(3)(D); and
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- The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any cash state supplemental rebates collected on the same percentage basis applied under the national rebate agreement.
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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State WASHINGTON

12.a. Prescribed Drugs (Cont.)

Preferred Drug List

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(A) The mail-order contractor is reimbursed at a mutually agreed upon level that is less than reimbursement provided to local retail pharmacies; and

(B) If authorized by the prescriber, the mail-order contractor may dispense the following drugs in up to a ninety-day supply:
  (i) Preferred drugs identified by the state;
  (ii) Generic drugs; and
  (iii) Drugs that do not require prior authorization or expedited prior authorization.

STATE OF WASHINGTON
SUPPLEMENTAL REBATE AGREEMENT

This Supplemental Rebate Agreement ("Agreement") is dated as of this ___day of _____, 200_, by and between the State of Washington Department of Social and Health Services ("State") and (name of provider).

RECITALS

WHEREAS, the State has the authority to enter into agreements with pharmaceutical manufacturers to collect supplemental rebates in addition to the rebates received under the CMS Rebate Agreement, pursuant to section 1927 of the Social Security Act (42 U.S.C. section 1396(r)(8) for the benefit of Washington's Medicaid recipients, providing such agreements are approved by the Center for Medicare and Medicaid Services (CMS); and

WHEREAS, (name of provider) is willing to provide supplemental rebates to the State based on the actual dispensing of (name of provider) Covered Products under the State's Medicaid program.

NOW THEREFORE, in consideration of the foregoing and of the representations, warranties and covenants set forth below, the parties, intending to be legally bound, agree as follows:

1. **Definitions.** As used herein, the following terms shall have the meanings set forth below:

1.1 **"Agreement"** means this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.

1.2 **"Average Wholesale Price ("AWP")"** shall mean the published price of the Covered Product by National Drug Code ("NDC") as published by First DataBank on the first day of the calendar quarter that corresponds to the calendar quarter for which the State utilization data for the Covered Product is reported to (name of provider).

1.3 **"Basic Rebate"** shall mean, with respect to the Covered Product, the quarterly payment by (name of provider) pursuant to (name of provider's) Medicaid Drug Rebate Agreement made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).

1.4 **"CMS"** shall mean the Center for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) of the U.S. Department of Health and Human services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

1.5 **"Competitive Product"** shall mean any (specific drug class) that competes with Covered Product. (e.g., any Proton Pump Inhibitor)

1.6 **"Covered Product"** shall mean (specific product(s) strength(s) dosage form) (e.g., "Prevacid 15mg and 30mg capsules.")

1.7 **"CPI Rebate"** means, with respect to the Covered Product, the quarterly payment by (name of provider) pursuant to (name of provider's) Medicaid Drug Rebate Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(3)).

1.8 **"Ingredient Reimbursement Basis"** shall mean the formula used by State to reimburse Pharmacy providers for branded pharmaceuticals.

1.9 **"Maximum Allowable Cost (MAC)"** shall mean the lowest reimbursement rate established by the State for generic (drug class).

1.10 **"Medicaid Drug Rebate Agreement"** shall mean the agreement in place between (name of provider) and the Secretary of Health and Human Services, pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508). CMS is the agency within HHS having the delegated authority to operate the Medicaid program.

1.11 **"Medicaid Recipient"** shall mean any person enrolled in the State Medicaid Program and eligible to receive prescription drug benefits under a fee for service arrangement.

1.12 **"Net Cost"** shall mean the prescription drug ingredient reimbursement calculated as (AWP - __ %) minus the sum of all rebates paid by (name of provider) to the State for the Covered Product for the calendar quarter. In the event of any change to the calculation used by the State to determine drug ingredient reimbursement paid by the State to Pharmacy providers, the applicable terms of this Agreement shall be amended to reflect such change.

1.13 **"Pharmacy"** shall mean a facility licensed to dispense legend drugs, and enrolled as a State Medicaid provider.

1.14 **"Preferred Drug List"** shall mean a document listing various pharmaceutical products covered by the State Medicaid Program for the purpose of guiding the prescribing, dispensing and acquisition of pharmaceutical products. The Preferred Drug List shall not prevent beneficiaries from obtaining access to medically necessary drugs of manufacturers that participate in the Medicaid Drug Rebate Program.

1.15 **"State Medicaid Program"** shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Recipients.

1.16 **"State Supplemental Rebate"** shall mean an amount paid on a calendar quarter basis by (name of provider) to State for utilization under State's fee for service Medicaid program pursuant tc this Agreement which renders at the option of the State, either (a) a net cost of Covered Products that is less than or equal to the cost of the competitive product for each quarter covered by the terms of this contract; or (b) a net cost that is comparatively low or that is the lowest net cost to an equivalent therapeutic dose of Covered Product to become a preferred drug in the drug class.

1.17 **"Unit"** means a single CMS unit of Covered Product.

1.18 **"USC"** means the United States Code. All references to this agreement to USC chapters or sections shall include any successor, amended, or replacement statute.

1.19 **"WAC"** means the Washington Administrative Code. All references in this Contract to WAC chapters or sections shall include any successor, amended, or replacement regulation.

2. **State Obligations**

2.1 **Preferred Drug List.** To be eligible for the Supplemental Rebates specified in Attachment B:

a) State shall place and maintain Covered Product on the Preferred Drug List, it being agreed that utilization shall be eligible for the State Supplemental Rebate only in quarters in which Covered Product is listed on the Preferred Drug List; and

b) State shall place Covered Products in an advantaged position relative to non-preferred Competitive Products regarding Preferred Drug List status, unless otherwise mutually agreed upon in writing by the State and (name of provider); and

c)Neither State nor State's fiscal agent will in any way disadvantage Covered Product through usages or restrictions not equally applied to other (drug class) on the Preferred Drug List, unless otherwise mutually agreed upon in writing by the State and (name of provider); and

d) State shall have on file the fully executed CMS Approval Letter, attached hereto as Exhibit C and incorporated by reference.

2.2 **Preferred Drug List Documentation and Publication.** State shall communicate the inclusion of Covered Product on the Preferred Drug List to State Medicaid Program providers through the standard notification process.

2.3 **Invoicing.** State shall invoice (name of provider) for State Supplemental Rebates separately from CMS Rebates using the format set forth by CMS (Reconciliation of State Invoice format). State shall submit the State Supplemental Rebate invoice to (name of provider) within sixty (60) days after the end of each calendar quarter in which the Covered Product subject to such State Supplemental Rebate was paid for by State. Any amended invoice shall be submitted by State within fifteen (15) months after the end of the calendar quarter in which Covered Product was paid for by State.

2.4 **Patient Information.** State, its agents, employees and contractors shall not provide to (name of provider) any patient identifiable information or protected health information ("PHI") or any other information prohibited or regulated by laws or regulations governing confidentiality of medical or other information.

2.5 **Approval of Generic.** If during the duration of this Agreement a generic equivalent of any Competitive Product should become available, State will allow Covered Product to remain on the Preferred Drug List so long as the net cost to the State, as defined in Attachment B, is not more than the lowest reimbursement cost as established by WAC 388-530-1300 for a generic equivalent.

2.6 **Competitive Product fluctuating net cost.** At the option of the State, the net cost of (name of provider's) Covered Products to Washington will be either (a) a net cost that is less than or equal to the cost of the competitive product for each quarter covered by the terms of this contract; or (b) a net cost that is comparatively low or that is the lowest net cost for an equivalent therapeutic dose of Covered Product to become a preferred drug in the drug class.

3. **(Name of Provider) Obligations**

3.1 **State Supplemental Rebate Payment.** (Name of provider) agrees to provide a State Supplemental Rebate for each of its Covered Products that is paid by the State and dispensed to Medicaid Recipients by Pharmacies for each calendar quarter that Covered Products are included in the Preferred Drug List. (Name of provider) shall pay to State the State Supplemental Rebate amount in accordance with the formula set forth in Attachment B. Nothing in this Agreement shall be construed to relieve (name of provider) from its obligation to pay Medicaid Drug Rebates for utilization by State Medicaid Recipients. State shall remit the appropriate share of the State Supplemental Rebate payments made under the Agreement to CMS as required under it s approved state plan.

3.2 **Payment Timeframe.** (Name of provider) shall pay to State the State Supplemental Rebate amount to which State is entitled in accordance with the formula set forth in Attachment B, within thirty-eight (38) days after receipt of State's invoice.

3.3 **Incomplete Submission.** (Name of provider) shall have no obligation to pay State Supplemental Rebate amounts for claims that are not submitted as part of an invoice in accordance with Section 2.3 of this Agreement. (Name of provider) shall notify State or its designee of any incomplete submission within thirty-eight (38) days of (name of provider's) receipt of such submission pursuant to Section 2.3.

3.4 **Over/Underpayment.** If either party discovers an error in the payment of State Supplemental Rebates, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally accepted applicable procedures followed by State or CMS in disputes concerning Medicaid Drug Rebates. Any overpayment shall be deducted from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, State will refund any such overpayment to (name of provider) within thirty (30) days of the parties' acknowledgement of the overpayment. (Name of provider) will remit any underpayment to State within thirty (30) days of the parties' acknowledgement of such underpayment.

3.5 **Discretion to Market.** Nothing in this Agreement shall be construed to prohibit (name of provider) from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that (name of provider) is liable for the payment of State Supplemental Rebates only for Covered Products (as identified by the 11-digit NDC code) distributed (directly or through the wholesale channel) to retail Pharmacies and dispensed to Medicaid Recipients. If (name of provider) elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, (name of provider) shall make every reasonable effort to notify State prior to such actions.

4. **Term and Termination**

4.1 **Effective Date.** This Agreement shall be effective as of (Month, day, year) and shall continue in force through (Month, day, year), unless it is terminated sooner pursuant to the following:

a) **Breach.** If either party commits a material breach of this Agreement, the non-breaching party shall deliver written notice mailed by certified mail, return receipt requested, of the alleged breach to the breaching party, with an opportunity for the breaching party to cure the breach during the thirty (30) day period following delivery. Failure to cure shall give the non-breaching party the right to cancel this Agreement at the end of the thirty (30) day period. The non-breaching party shall give the breaching party final written notice of the cancellation of this Agreement.

b) **Without Cause.** Either party may terminate this Agreement without cause as of the end of any calendar quarter by giving the other party ninety (90) days prior written notice.

4.2 **Accrued Obligations/Remedies.** The expiration or termination of this Agreement shall not affect any rights or obligations of the parties that have accrued prior to the effective date of such termination. The fact that either party exercises any right of termination it may have under this Agreement shall not prevent such party from pursuing any other remedy it may be entitled to in law or equity. Any remedy provided herein shall not be deemed an exclusive remedy unless expressly provided for as such.

4.3 **Execution, Amendment, and Waiver.** This Agreement shall be binding only upon signature by both parties. This Agreement, or any provision, may be altered, amended, or waived by a written amendment executed by both parties. Any alterations or amendments to the Agreement must be authorized by CMS.

5 **Miscellaneous**

5.1 **Record Keeping and Audit.** During the term of this Agreement and for a period of three (3) years thereafter, both parties to the Agreement shall use reasonable efforts at all times to ensure that they maintain accurate books, files and records relevant to this Agreement. At (name of provider's) written request, State shall make such information available for inspection by (name of provider) representatives or its designated auditors during regular business hours. Upon written request, each party shall otherwise have the right to inspect, up to once each year, all such relevant books and records of the other party to verify compliance with the terms of this Agreement.

5.2 **Indemnification.** (Name of provider) shall be responsible for and shall indemnify and hold State harmless from all claims resulting from the acts or omissions of (name of provider) and any Subcontractor. State shall be responsible and shall indemnify and hold (name of provider) harmless from all claims resulting from the acts or omissions of State.

5.3 **Confidentiality.** Except as otherwise may be required to be disclosed by law and in accordance with the Rebate Agreement between the Secretary of Health and Human Services and the drug manufacturers, information disclosed by (name of provider) in connection with this Agreement will not be disclosed by the State. Each party shall maintain the confidentiality of all the terms and conditions of this Agreement throughout the term hereof and for a period of three (3) years thereafter.

5.4 **Notices.** Any notice required or permitted to be given by either party to the other shall be given in person or sent by first class mail or express delivery, addressed to the other party at the address set forth below.